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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/691,928	GOLDSTEIN ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

OFFICIAL ACTION

Acknowledgement of Receipt

Receipt of the Applicants' Appeal Brief, which was filed on September 1, 2006, in response to the Advisory Action dated July 27, 2006, is acknowledged.

Withdraw of Finality & Reopening of Prosecution

Upon further reconsideration, the finality of the Official Action dated March 23, 2006, is hereby withdrawn, and prosecution reopened in favor of the new rejections set forth hereinbelow in the instant **Non-Final** Official Action.

Status of Claims

The amendment to claims 1 and 3, as set forth in the after final Response, was not entered. Claims 1, 2, 4, 7 and 14 were amended, and claim 17 was added, by a Substitute Amendment that was filed on December 27, 2005. As a result, claims 1-17 as presented in the aforementioned Substitute Amendment are currently pending and therefore examined herein on the merits for patentability.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112, which forms the basis of the claim rejection as set forth under this particular section of the Official Action:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim as amended introduces new matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors,

at the time the application was filed, had possession of the claimed invention. More specifically, claim 1 recites a "low-medium potency steroidal anti-inflammatory." Applicants rely on page 2, lines 7-10 and page 3, lines 19-21, in particular, of the instant specification, which states in relevant part that "[o]ther non-halogenated or low to medium potency corticosteroids could be substituted for desonide," as providing support for the newly added claim limitation "low-medium potency steroidal anti-inflammatory." See [0006] and [0010] of U.S. Pre-Grant Patent Application Publication 2004/0138179 (the Goldstein '179 publication), which is the published version of the instant application. However, inadequate support exists in the specification as originally filed for amending said claim to recite a "low-medium potency" steroidal anti-inflammatory, as Applicants' reliance on the phrase "low to medium potency" is reasonably interpreted by the Examiner to mean "low [potency] to medium potency," especially in light of the fact that the only list of steroidal anti-inflammatory compounds provided within the specification as originally filed for incorporation into the composition of the instant application, include desoximetasone and mometasone, both of which may be considered to constitute *high-medium potency* and *medium potency* steroidal anti-inflammatory compounds, respectively. Applicants are requested to delete the phrase "to low-medium" from claim 1.

Claim 1 is further rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim as amended introduces new matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. More specifically, claim 1 recites "a low to low-medium potency steroidal anti-inflammatory ... having a higher potency than 1 wt% hydrocortisone." Applicants rely on page 5, lines 13-15, of the instant specification, which states in relevant part that "hydrocortisone [present in an amount of] 1% [by

weight] ... would be minimally effective, if effective at all, in treating the significant inflammation that accompanies fungal disease," as providing support for the newly added claim limitation. See [0023] of the Goldstein '179 publication. However, inadequate support exists in the specification as originally filed for amending said claim to recite a low to low-medium potency steroidal anti-inflammatory "having a higher potency than 1 wt% hydrocortisone," thereby resulting in the addition of new matter. Appropriate correction is required. Applicants are requested to delete the phrase "having a higher potency than 1 wt% hydrocortisone" from claim 1.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112, which forms the basis of the claim rejections as set forth under this particular section of the Official Action:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. With respect to claim 1, confusion exists as to what steroids constitute a "low-medium potency steroidal anti-inflammatory?" More specifically, the phrase a "low-medium potency steroidal anti-inflammatory" renders said claim indefinite because the meets and bounds of said claim is unclear, as confusion exists with respect to the intended scope of said claim. See MPEP § 2173.05(d).

While the specification as originally filed explicitly discloses that desonide is a low potency steroidal anti-inflammatory and that "other non-halogenated or low to medium potency corticosteroids could be substituted for desonide," no where within the specification as originally filed discloses specific examples of what constitutes a "low-medium potency steroidal anti-inflammatory." See

[0006], [0007] and [0010] of the Goldstein '179 publication. Since Applicants have not clearly defined what constitutes a low-medium potency steroidal anti-inflammatory, it is unclear how potent a steroidal anti-inflammatory compound can be before it is no longer considered, within the confines of the specification as originally filed, to be within the realm of a low-medium potency steroidal anti-inflammatory as instantly claimed. It should be mentioned however that while [0023] of the Goldstein '179 publication generically discloses a list of steroidal anti-inflammatory compounds for incorporation into the composition of the instant application, including, but not limited to, desoximetasone and mometasone, both of which may be considered to constitute *high-medium potency* and *medium potency* steroidal anti-inflammatory compounds, respectively, along with desonide, which is a low potency steroidal anti-inflammatory, confusion exists as to what compounds would constitute a low-medium potency steroidal anti-inflammatory, due to an utter lack of guidance, or even a scintilla of supporting disclosure, within the specification as originally filed defining what constitutes a low-medium potency steroidal anti-inflammatory compound.

Claims 2-17, which are dependent upon and include all of the limitations of independent claim 1, are therefore likewise rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Appropriate correction is required

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102, which forms the basis of the anticipation rejections as set forth under this particular section of the Official Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Upon further consideration, the rejection of claims 1-10 and 13-17 under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent 6,444,647 (the Robinson '647 patent) is hereby withdrawn.

2. Upon further consideration, the rejection of claims 1-5, 7-13 and 17 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 6,075,056 (the Quigley '056 patent) is hereby withdrawn.

3. Upon further consideration, the rejection of claims 1-9, 13, 14, 16 and 17 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,686,089 (the Mitra '089 patent) is hereby withdrawn.

4. Upon further consideration, the rejection of claims 1-10 and 17 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,219,877 (the Shah '877 patent) is hereby withdrawn.

5. Claims 1-3, 7-10 and 13-17 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Pre-Grant Patent Application Publication 2003/0232086 (the McCadden '086 publication).

With respect to claims 1-3, 7-10 and 13-17 of the instant application, the McCadden '086 publication discloses a method of treating a pediatric patient, including infants, infected with a tinea or

candida fungal disease comprising topically administering to the skin of said pediatric patient an antifungal steroidal composition from two times per day to four times per day (abstract; [0002], [0013], [0015], [0026], [0027], [0076], [0077]); wherein said antifungal steroidal composition comprises: an antifungal agent present in an amount of up to about 7 wt. %, preferably from about 0.5 wt. % to about 5 wt. %, and more preferably from about 1 wt. % to about 2 wt. %, and is selected from the group consisting of ciclopirox, clotrimazole, econazole, ketoconazole, miconazole, terbinafine, terconazole, and tioconazole ([0020], [0066], [0067], [0077]-[0079], [0122], [0123]); and a steroidal anti-inflammatory agent present in an amount of up to about 5 wt. %, preferably from about 0.0005 wt. % to about 5 wt. % and is selected from the group consisting of alclometasone dipropionate, desonide, fluocinolone acetonide, hydrocortisone butyrate, and hydrocortisone valerate ([0020], [0025]-[0029], [0034], [0037]-[0040], [0042], [0044], [0077]-[0079], [0123]); wherein said antifungal steroidal composition further comprises up to about 60 wt. % of one or more pharmaceutically acceptable excipients selected from the group consisting of well known solvents (i.e., propylene glycol), emollients (i.e., mineral oil), humectants (i.e., sorbitol), preservatives (i.e., benzyl alcohol), emulsifiers (i.e., glyceryl monosterate), buffers (i.e., hydrochloric acid, sodium hydroxide and monobasic sodium phosphate) and mixtures thereof ([0020], [0073]); wherein said antifungal steroidal composition is formulated as a cream, ointment, gel, lotion, spray, or solution for topical administration ([0017], [0021], [0022], [0065]).

6. Claims 1-3, 7-10, 13 and 17 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,219,877 (the Shah '877 patent).

With respect to claims 1-3, 7-10, 13 and 17 of the instant application, the Shah '877 patent discloses an antifungal steroidal composition for the topical treatment of a tinea or candida fungal disease (abstract; column 1, lines 6-14), wherein said composition comprises: an antifungal agent present in an amount of from 0.1 wt. % to 5 wt. % and is selected from the group consisting of clotrimazole, econazole and miconazole (column 3, lines 4-14 and 43-53); and a steroidal anti-inflammatory agent present in an amount of from 0.01 wt. % to 2.5 wt. % and is selected from the group consisting of desonide, fluocinolone acetonide, hydrocortisone butyrate, and hydrocortisone valerate (column 3, lines 4-14 and 54-68; column 4, lines 1-16); wherein said composition is formulated as a gel for topical administration (column 3, lines 20-25).

7. Claims 1-3, 7-13 and 17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 6,075,056 (the Quigley '056 patent).

With respect to claims 1-3, 7-13 and 17 of the instant application, the Quigley '056 patent discloses an antifungal steroidal composition for the topical treatment of a tinea or candida fungal disease (abstract, and column 7, lines 25-30), wherein said composition comprises: an antifungal agent, such as terbinafine, present in an amount of from 0.5 wt. % to 5 wt. % (abstract; column 2, line 6; claim 2); and a steroidal anti-inflammatory agent is present in an amount of from 0.001 wt. % to 5.0 wt. % (column 5, lines 56-58) and is selected from the group consisting of aclometasone dipropionate, desonide, fluocinolone acetonide, hydrocortisone, hydrocortisone butyrate, and hydrocortisone valerate (column 5, lines 1-50); wherein said composition further comprises a pharmaceutically acceptable excipient selected from the group consisting of well known solvents (i.e., propylene glycol), emollients (i.e., mineral oil), humectants (i.e., sorbitol), preservatives (i.e., benzyl alcohol), emulsifiers (i.e.,

glyceryl monosterate), buffers (i.e., hydrochloric acid, sodium hydroxide and monobasic sodium phosphate) and mixtures thereof (column 2, lines 53-67; column 3, lines 1-8); wherein said composition has a pH from about 3.5 to about 7.0 (column 3, lines 1-2) and is formulated as a cream, ointment, gel, lotion, foam, powder, aerosol, spray, shampoo or liquid solution for topical administration (column 7, lines 31-34).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Upon further consideration, the rejection of claim 15 under 35 U.S.C. § 103(a) as being unpatentable over the teachings of U.S. Patent 5,686,089 (the Mitra '089 patent) is hereby withdrawn.

2. Claims 4-6, 11 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pre-Grant Patent Application Publication 2003/0232086 (the McCadden '086 publication).

The McCadden '086 publication teaches a method of treating a pediatric patient, including infants, infected with a tinea or candida fungal disease comprising topically administering to the skin of said pediatric patient an antifungal steroidal composition from two times per day to four times per day (abstract; [0002], [0013], [0015], [0026], [0027], [0076], [0077]); wherein said antifungal steroidal composition comprises: an antifungal agent present in an amount of up to about 7 wt. %, preferably from about 0.5 wt. % to about 5 wt. %, and more preferably from about 1 wt. % to about 2 wt. %, and is selected from the group consisting of ciclopirox, clotrimazole, econazole, ketoconazole, miconazole, terbinafine, terconazole, and tioconazole ([0020], [0066], [0067], [0077]-[0079], [0122], [0123]); and a steroidal anti-inflammatory agent present in an amount of up to about 5 wt. %, preferably from about 0.0005 wt. % to about 5 wt. % and is selected from the group consisting of alclometasone dipropionate, desonide, fluocinolone acetonide, hydrocortisone butyrate, and hydrocortisone valerate ([0020], [0025]-[0029], [0034], [0037]-[0040], [0042], [0044], [0077]-[0079], [0123]); wherein said antifungal steroidal composition further comprises up to about 60 wt. % of one or more pharmaceutically acceptable excipients selected from the group consisting of well known solvents (i.e., propylene glycol), emollients (i.e., mineral oil), humectants (i.e., sorbitol), preservatives (i.e., benzyl alcohol), emulsifiers (i.e., glyceryl monosterate), buffers (i.e., hydrochloric acid, sodium hydroxide and monobasic sodium phosphate) and mixtures thereof ([0020], [0073]); wherein said antifungal steroidal composition is formulated as a cream, ointment, gel, lotion, spray, or solution for topical administration ([0017], [0021], [0022], [0065]).

With respect to claims 4-6 of the instant application, the McCadden '086 publication does not explicitly teach a specific embodiment of said antifungal steroidal composition comprising the particular combination of said clotrimazole antifungal agent together with said desonide steroidal anti-inflammatory.

However, the McCadden '086 publication does teach a specific embodiment of said antifungal steroidal composition comprising said clotrimazole antifungal agent, which is present in a Markush group of only five other antifungal agents, in combination with said desonide steroidal anti-inflammatory, which is present in a Markush group of only two other steroidal anti-inflammatory compounds, one of which is hydrocortisone ([0077]). In addition, the McCadden '086 publication teaches a specific embodiment of said antifungal steroidal composition comprising the particular combination of said clotrimazole antifungal agent together with said low-potency hydrocortisone steroidal anti-inflammatory ([0077], [0123]). Furthermore, the McCadden '086 publication teaches the interchangeability of desonide and hydrocortisone in that desonide and hydrocortisone are both low-potency steroidal anti-inflammatory compounds useful for imparting desired therapeutic anti-inflammatory properties with little or no risk of causing skin atrophy or negative systemic side effects in pediatric patients including infants ([0026]-[0028], [0038]).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the specific embodiment of said antifungal steroidal composition comprising the particular combination of said clotrimazole antifungal agent together with said low-potency hydrocortisone steroidal anti-inflammatory of the McCadden '086 publication by substituting said low-potency desonide steroidal anti-inflammatory in place of said low-potency hydrocortisone steroidal anti-inflammatory, because the McCadden '086 publication reasonably teaches the

interchangeability of said low-potency desonide steroidal anti-inflammatory with said low-potency hydrocortisone steroidal anti-inflammatory. One of ordinary skill in the art would have been motivated, as well as had a reasonable expectation of success, to substitute said low-potency desonide steroidal anti-inflammatory for said low-potency hydrocortisone steroidal anti-inflammatory within said antifungal steroidal composition comprising said clotrimazole antifungal agent, so as to impart desired therapeutic antifungal and anti-inflammatory properties to said antifungal steroidal composition with little or no risk of causing skin atrophy and/or negative systemic side effects in pediatric patients, including infants, as reasonably suggested by the McCadden '086 publication.

With respect to claims 11 and 12 of the instant application, the McCadden '086 publication does not explicitly teach a pH of about 3.5 to about 7.0. However, the McCadden '086 publication does teach that said antifungal steroidal composition comprises pH buffers and that said antifungal steroidal composition is safe for topical administration to pediatric patients, including infants. It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed that the antifungal steroidal composition of the McCadden '086 publication would have a neutral or substantially neutral (i.e., slightly acidic or slightly basic) pH so as not to be irritating to the skin of said pediatric patient, especially given the extreme sensitivity of the skin of infants. One of ordinary skill in the art would have been motivated to formulate said antifungal steroidal composition comprising said pH buffers in a manner such that said antifungal steroidal composition would have a neutral or substantially neutral (i.e., slightly acidic or slightly basic) pH so as not to be irritating to the skin of said pediatric patient, especially given the extreme sensitivity of the skin of infants, thereby facilitating patient compliance and the corresponding therapeutic benefits associated with the administration thereof.

3. Claims 4-6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,219,877 (the Shah '877 patent).

The teachings of the Shah '877 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 4-6 of the instant application, the Shah '877 patent does not explicitly teach a specific embodiment of said antifungal steroidal composition comprising the particular combination of said clotrimazole antifungal agent together with said desonide steroidal anti-inflammatory.

However, the Shah '877 patent does teach an antifungal steroidal composition for the topical treatment of a tinea or candida fungal disease (abstract; column 1, lines 6-14), wherein said composition comprises: an antifungal agent present in an amount of *from 0.1 wt. % to 5 wt. %* and is selected from the group consisting of *clotrimazole*, econazole and miconazole (column 3, lines 4-14 and 43-53); and a steroidal anti-inflammatory agent present in an amount of *from 0.01 wt. % to 2.5 wt. %* and is selected from the group consisting of *desonide*, fluocinolone acetonide, hydrocortisone butyrate, and hydrocortisone valerate (column 3, lines 4-14 and 54-68; column 4, lines 1-16); wherein said composition is formulated as a gel for topical administration (column 3, lines 20-25).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to formulate an antifungal steroidal composition comprising the particular combination of said clotrimazole antifungal agent together with said low-potency hydrocortisone steroidal anti-inflammatory. One of ordinary skill in the art would have been motivated, as well as had a reasonable expectation of success, to formulate an antifungal steroidal composition comprising the particular combination of said clotrimazole antifungal agent together with said low-potency

hydrocortisone steroidal anti-inflammatory, so as to impart desired therapeutic antifungal and anti-inflammatory properties to said antifungal steroidal composition, as reasonably suggested by the Shah '877 patent.

4. Claims 11 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Shah '877 patent in view of the Quigley '056 patent.

The teachings of the Shah '877 patent and the Quigley '056 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

The Shah '877 patent teaches an antifungal steroidal composition for the topical treatment of a tinea or candida fungal disease, wherein said composition comprises: an antifungal agent; and a steroidal anti-inflammatory agent; wherein said composition is formulated as a gel for topical administration.

The Shah '877 patent does not explicitly teach an antifungal steroidal composition further comprising a pharmaceutically acceptable excipient selected from the group consisting of well known solvents (i.e., propylene glycol), emollients (i.e., mineral oil), humectants (i.e., sorbitol), preservatives (i.e., benzyl alcohol), emulsifiers (i.e., glyceryl monosterate), buffers (i.e., hydrochloric acid, sodium hydroxide and monobasic sodium phosphate) and mixtures thereof, as claimed in claims 11 and 12.

However, the Quigley '056 patent teaches an antifungal steroidal composition for the topical treatment of a tinea or candida fungal disease, wherein said composition comprises: an antifungal agent; a steroidal anti-inflammatory agent; and a pharmaceutically acceptable excipient selected from the group consisting of well known solvents (i.e., propylene glycol), emollients (i.e., mineral oil), humectants (i.e., sorbitol), preservatives (i.e., benzyl alcohol), emulsifiers (i.e., glyceryl monosterate),

buffers (i.e., hydrochloric acid, sodium hydroxide and monobasic sodium phosphate) and mixtures thereof; wherein said composition has a pH from about 3.5 to about 7.0 and is formulated as a cream, ointment, gel, lotion, foam, powder, aerosol, spray, shampoo or liquid solution for topical administration.

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the antifungal steroidal composition of the Shah '877 patent by incorporating therein a pharmaceutical excipient selected from the group consisting of well known solvents (i.e., propylene glycol), emollients (i.e., mineral oil), humectants (i.e., sorbitol), preservatives (i.e., benzyl alcohol), emulsifiers (i.e., glyceryl monosterate), buffers (i.e., hydrochloric acid, sodium hydroxide and monobasic sodium phosphate) and mixtures thereof, wherein said composition has a pH from about 3.5 to about 7.0, as taught by the Quigley '056 patent, especially since both prior art references teach utilizing said antifungal steroidal compositions for the topical treatment of a tinea or candida fungal disease, wherein said antifungal steroidal compositions are formulated in a manner so as to facilitate the topical administration thereof. One of ordinary skill in the art at the time the instant application was filed would have been motivated to incorporate a pharmaceutical excipient selected from the group consisting of well known solvents (i.e., propylene glycol), emollients (i.e., mineral oil), humectants (i.e., sorbitol), preservatives (i.e., benzyl alcohol), emulsifiers (i.e., glyceryl monosterate), buffers (i.e., hydrochloric acid, sodium hydroxide and monobasic sodium phosphate) and mixtures thereof, wherein said composition has a pH from about 3.5 to about 7.0, as taught by the Quigley '056 patent, into the antifungal steroidal composition of the Shah '877 patent, so as to render a formulation of said antifungal steroidal composition of the Shah '877 patent suitable for the topical administration

thereof, thereby promoting drug delivery of said antifungal and said steroidal anti-inflammatory to the skin infected with a tinea or candida fungal disease.

5. Claims 14-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Shah '877 patent in view of U.S. Patent 5,686,089 (the Mitra '089 patent).

The teachings of the Shah '877 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 14-16 of the instant application, the Shah '877 patent does not explicitly teach a method of treating said tinea or candida fungal disease by topically administering said antifungal steroidal composition to a child (under ten years of age) in need thereof, wherein said method comprises: applying said antifungal steroidal composition twice per day to areas of the skin infected with said tinea or candida fungal disease.

However, the Mitra '089 patent teaches a method of treating an individual infected with a candida fungal disease (column 3, lines 1-13; column 8, lines 66 and 67) comprising topically administering an antifungal steroidal composition to said individual two times per day in an amount dependent upon the personal needs of said individual, which typically ranges from about 1 mg per cm^2 of skin to about 2 mg per cm^2 of skin (column 8, lines 66-68; and column 9, lines 1-16); wherein said antifungal steroidal composition comprises an antifungal agent (column 3, lines 35-40) and a steroidal anti-inflammatory agent (column 6, lines 65-67; and column 7, lines 1-29); wherein said antifungal agent is selected from the group consisting of clotrimazole, miconazole, terconazole and nystatin, wherein said antifungal agent is present in an amount from about 0.01% to about 4% by weight of said composition (column 3, lines 35-40; and claim 1); wherein said steroidal anti-inflammatory agent is

selected from the group consisting of desonide, fluocinolone acetonide, and hydrocortisone valerate, wherein said steroidal anti-inflammatory agent is present in an amount from about 0.1% to about 10.0% by weight of said composition (column 6, lines 65-67; and column 7, lines 1-29).

Although the Mitra '089 patent does not explicitly teach that said individual infected with said candida fungal disease is a child under ten years of age, the Mitra '089 patent does teach considering the personal needs of said infected individual, with respect to the number of applications of said antifungal steroidal composition, as well as the amount thereof. It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to topically administer the antifungal steroidal composition of the Shah '877 patent, to an individual (including children under ten years of age) suffering from a tinea or candida fungal disease, by applying said antifungal steroidal composition to said individual two times per day in an amount dependent upon the personal needs of said individual, which typically ranges from about 1 mg per cm^2 of skin to about 2 mg per cm^2 of skin, as reasonably suggested by the Mitra '089 patent. One of ordinary skill in the art would have been motivated to topically administer the antifungal steroidal composition of the Shah '877 patent, to an individual (including children under ten years of age) suffering from a tinea or candida fungal disease, by applying said antifungal steroidal composition to said individual two times per day in an amount dependent upon the personal needs of said individual, which typically ranges from about 1 mg per cm^2 of skin to about 2 mg per cm^2 of skin, as reasonably suggested by the Mitra '089 patent, so as to treat said individual (including children under ten years of age) suffering from said tinea or candida fungal disease, while avoiding adverse complications and side effects that may result from administering said drug containing antifungal steroidal composition either too often, in too large of a dose, or both.

6. Claims 14-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Shah '877 patent in view of U.S. Patent 6,444,647 (hereinafter the Robinson '647 patent).

The teachings of the Shah '877 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 14-16 of the instant application, the Shah '877 patent does not explicitly teach a method of treating said tinea or candida fungal disease by topically administering said antifungal steroidal composition to a child (under ten years of age) in need thereof, wherein said method comprises: applying said antifungal steroidal composition twice per day to areas of the skin infected with said tinea or candida fungal disease.

However, the Robinson '647 patent teaches a method of treating fungal diseases of the skin and/or nails of a subject (column 3, lines 6-13; column 4, lines 1-13; column 30, lines 14-50) comprising topically administering an antifungal steroidal composition to the skin and/or nails of said subject during the subjects lifetime (which reads on children under ten years of age) about once to about three times per day in an amount from about 0.1 mg/cm^2 to about 10 mg/cm^2 (column 36, lines 51-67; and column 37, lines 1-51); wherein said antifungal steroidal composition may comprise: an antifungal agent selected from the group consisting of clotrimazole, ketoconazole, miconazole and nystatin, which is present in an amount from 0.001 wt. % to 10 wt. % (column 30, lines 14-50); and a steroidal anti-inflammatory agent selected from the group consisting of desonide, fluocinolone acetonide, hydrocortisone butyrate, and hydrocortisone valerate, which is present in an amount from 0.1 wt. % to 10.0 wt. % (column 26, lines 65-68; column 27, lines 1-33); wherein said composition is formulated as a cream, ointment, gel, lotion, foam, powder, spray, shampoo, or liquid solution for topical administration (column 20, lines 64-67; and column 37, lines 6-10).

Although the Robinson '647 patent does not explicitly teach that said subject infected with said fungal disease is a child under ten years of age, the Robinson '647 patent does teach applying said antifungal steroidal composition to said subject during the subjects lifetime, which reads on children under ten years of age. It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to topically administer the antifungal steroidal composition of the Shah '877 patent, to a subject suffering from a tinea or candida fungal disease during said subjects lifetime (including children under ten years of age), by applying said antifungal steroidal composition to said subject about once to about three times per day in an amount from about 0.1 mg/cm^2 to about 10 mg/cm^2, as reasonably suggested by the Robinson '647 patent. One of ordinary skill in the art would have been motivated to topically administer the antifungal steroidal composition of the Shah '877 patent, to a subject suffering from a tinea or candida fungal disease during said subjects lifetime (including children under ten years of age) by applying said antifungal steroidal composition to said subject about once to about three times per day in an amount from about 0.1 mg/cm^2 to about 10 mg/cm^2, as reasonably suggested by the Robinson '647 patent, so as to treat said subject (including children under ten years of age) suffering from said tinea or candida fungal disease, while avoiding adverse complications and side effects that may result from administering said drug containing antifungal steroidal composition either too often, in too large of a dose, or both.

Conclusion

Claims 1-17 are rejected because the claimed invention would have been anticipated and/or prima facie obvious to one of ordinary skill in the art at the time the invention was made since each and every element of the claimed invention, as a whole, is disclosed in and/or would have been reasonably suggested by the teachings of the cited prior art references.

Reinstatement of Appeal

If an Appellant wishes to reinstate an appeal after prosecution is reopened, Appellant must file a new notice of appeal in compliance with 37 CFR § 41.31 and a complete new appeal brief in compliance with 37 CFR § 41.37. Any previously paid appeal fees set forth in 37 CFR § 41.20 for filing a notice of appeal, filing an appeal brief, and requesting an oral hearing (if applicable) will be applied to the new appeal on the same application as long as a final Board decision has not been made on the prior appeal. If, however, the appeal fees have increased since they were previously paid, then Appellant must pay the difference between the current fee(s) and the amount previously paid. Appellant must file a complete new appeal brief in compliance with the format and content requirements of 37 CFR 41.37(c) within two months from the date of filing the new notice of appeal. See MPEP § 1205.

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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